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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,376	05/19/2004	Dwight McKee	382/9-1801	6519
28147	7590	11/02/2004	EXAMINER	
WILLIAM J. SAPONE COLEMAN SUDOL SAPONE P.C. 714 COLORADO AVENUE BRIDGE PORT, CT 06605				COE, SUSAN D
ART UNIT		PAPER NUMBER		
		1654		

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/849,376	MCKEE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Susan D. Coe	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 20 October 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 14-27 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-13 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

1. Claims 1-27 are currently pending.

### ***Election/Restrictions***

2. Applicant's election of Group I, claims 1-13 and vitamins for species A in the reply filed on October 20, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 14-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on October 20, 2004.

4. Claims 1-13 are examined on the merits.

### ***Specification***

The use of the trademark Manapol has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite because it states that the composition comprises an “aloe vera extract including acemannan, l-glutamine, and l-glycine.” It is unclear if the claim intends for the acemannan, l-glutamine, and l-glycine to be additional ingredients added to the aloe vera extract or if the claim is simply describing ingredients that are naturally found in the aloe vera extract.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 8, 12 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Herbal Fields website describing Aloe vera  
  
(<http://web.archive.org/web/20020615000734/http://herbalfields.com/aloe.html>) June 9, 2002.

Applicant's claims are drawn to a composition that comprises aloe vera, acemannan, glutamine, glycine, and vitamins.

The Herbal Fields website teaches that aloe vera contains acemannan, glutamine, glycine and vitamins (see page 2). The website teaches that the aloe vera treats ailments related to the upper gastrointestinal tract (see page 1). The reference teaches aloe vera formulated in capsules (see page 3).

7. Claims 1, 8, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by CSL website about aloe (<http://web.archive.org/web/2002022223322/http://aloe-vera.com/learnaboutaloe.html>) - February 20, 2002.

The CSL website teaches that aloe vera naturally contains acemannan (see page 7), glutamine, glycine (see page 10), and vitamins (see page 9). The website teaches that aloe vera has numerous healing properties including treatment of ailments related to the upper gastrointestinal tract. These uses also disclose unit doses of aloe (see pages 3-6).

8. Claims 1, 8, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/00186 in light of CSL website about aloe (<http://web.archive.org/web/2002022223322/http://aloe-vera.com/learnaboutaloe.html>) - February 20, 2002 as evidence of inherency.

WO '186 teaches a composition that contains aloe vera, glycine, glutamine, and vitamins (see pages 32-34; Example 12). This composition is in a unit dose form as a topical cream.

The reference does not specifically teach that the composition contains acemannan. However, as discussed above, the CSL website teaches that acemannan naturally contains acemannan. Thus, the aloe used in the composition of WO '186 would inherently contain

acemannan. Therefore, WO '186 teaches a composition that contains aloe, acemannan, glycine, glutamine, and vitamins.

WO '186 also does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

9. Claims 1, 4, 8, 9, 12, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. Pub. No. 2002/0084912 A1 in light of CSL website about aloe (<http://web.archive.org/web/2002022223322/http://aloe-vera.com/learnaboutaloe.html>) - February 20, 2002 as evidence of inherency.

US '912 teaches a composition that contains aloe, glycine, glutamine, and vitamins (see claim 5). The composition is in unit dose form (see claim 15). The ingredients are present in amounts from 30 to 100mg (see paragraph 87).

The reference does not specifically teach that the composition contains acemannan. However, as discussed above, the CSL website teaches that acemannan naturally contains acemannan. Thus, the aloe used in the composition of US '912 would inherently contain acemannan. Therefore, US '912 teaches a composition that contains aloe, acemannan, glycine, glutamine, and vitamins.

US '912 also does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbal Fields website describing Aloe vera

(<http://web.archive.org/web/20020615000734/http://herbalfIELDS.com/aloe.html>) June 9, 2002.

As discussed above, this website teaches a composition that contains aloe vera, acemannan, glycine, glutamine, and vitamins; however, the reference does not specifically teach using the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is a result effective parameter that is considered obvious to optimize. A person of skill in the art would routinely vary the amount of aloe vera to use in order to best achieve the pharmaceutical effects taught by the reference. This variation of aloe vera amount would also vary the amount of acemannan, glutamine, glycine, and vitamins present in the composition.

11. Claims 1-7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over CSL website about aloe (<http://web.archive.org/web/2002022223322/http://aloe-vera.com/learnaboutaloe.html>) - February 20, 2002.

As discussed above, this website teaches a composition that contains aloe vera, acemannan, glycine, glutamine, and vitamins; however, the reference does not specifically teach using the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is a result effective parameter that is considered obvious to optimize. A person of skill in the art would routinely vary the amount of aloe vera to use in order to best achieve the pharmaceutical effects taught by the reference. This variation of aloe vera amount would also vary the amount of acemannan, glutamine, glycine, and vitamins present in the composition.

12. Claims 1-7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/00186.

As discussed above, WO '186 teaches a composition that comprises aloe, acemannan, glutamine, and glycine. However, the reference does not specifically teach using the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is a result effective parameter that is considered obvious to optimize. A person of skill in the art would routinely vary the amount of aloe vera to use in order to best achieve the pharmaceutical effects taught by the reference. This variation of aloe vera amount would also vary the amount of acemannan present in the composition.

13. Claims 1-7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. Pub. No 2003/0084912.

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As discussed above, US '912 teaches a composition that comprises aloe, acemannan, glutamine, and glycine. However, the reference does not specifically teach using the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is a result effective parameter that is considered obvious to optimize. A person of skill in the art would routinely vary the amount of aloe vera to use in order to best achieve the pharmaceutical effects taught by the reference. This variation of aloe vera amount would also vary the amount of acemannan present in the composition.

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Susan D. Coe, Examiner

October 27, 2004